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I. EXECUTIVE SUMMARY

1. In his Sur-Reply Declaration, Mr. Young makes a variety of incorrect assertions concerning the contracts referenced in his Declaration; he omits significant relevant contracts; and his conclusions are not supported by, in fact are contrary to, the evidence. Two primary erroneous assertions are particularly troubling, *i.e.*, (1) that the AWP does not serve as a basis for reimbursement rates negotiated by commercial payors for physician-administered drugs; and, (2) that AWP (which are NDC-specific) could not be relied upon by commercial payors for reimbursement for physician-administered drugs since physicians submit reimbursement claims based upon J-Codes, not NDCs.

2. In responding to Mr. Young, this Declaration proceeds as follows. In Section I, I address and demonstrate Mr. Young's misrepresentation of the information included in the reimbursement contracts upon which he relies for his analysis. In Section II, I discuss his incorrect assertion that the use of J-Codes renders unusable the formulaic damage methodology that I have previously put forward. In Section III, I address the issue of aggregate class-wide damage calculation in light of Mr. Young's Sur-Reply and this Rebuttal.

II. MR. YOUNG INCORRECTLY ASSERTS THAT COMMERCIAL PAYOR CONTRACTS WITH PHYSICIANS DO NOT REFERENCE AWP.

3. In his Exhibit 2, Mr. Young asserts that he reviewed 206 physician contracts and only nine contracts reference AWP. In a footnote to his Exhibit 2, he asserts that he has reviewed an additional 138 "such documents" and only four reference AWP. He concludes that Class members reimburse for physician-administered drugs at rates unrelated to AWP.

4. This conclusion fails for the following reasons.

(a) First, this conclusion is based upon a sample of contracts for a small number of payors, a sample which is unrepresentative. Mr. Young provides no basis for concluding that such a sampling is sufficient for drawing conclusions concerning the behavior of thousands of payors.

(b) Second, this conclusion is actually not supported by his unrepresentative sample of contracts. Indeed, based upon a more careful review of his contractual evidence, his conclusion is demonstrably untrue. Mr. Young mischaracterizes the import of the contracts and spuriously overstates the evidence in his favor. For example, as explained below, there are cases in which he reports contracts that he alleges do not reference AWP (but they do) while he excludes relevant sequential Bates-numbered contracts that explicitly do reference AWP.

(c) Third, his conclusion is contradicted by evidence for the industry as a whole, as described in my Affirmative Declaration (Attachments C and D) and as corroborated by Dr. Berndt (at pp. 15, 23-24).

5. Let me develop these criticisms more fully.

(a) Some of the contracts (8%) characterize contractual reimbursement rates negotiated *prior* to the Class Period; any findings from such contracts are irrelevant.

(b) Many documents purported to be contracts have *nothing to do with pharmaceuticals or reimbursement for pharmaceuticals*; indeed, some are mere one-page letters referring to such medical procedures.¹ A number of contracts are specifically for physician services that do not involve injectible drugs; for example, OB-GYN and general surgical services. Such contracts neither need nor would have any reference to drug reimbursement or AWP, even when AWP is the basis for drug reimbursement for that commercial payor.

¹ For examples, see AET 003990, AET 004085 and AET 004086-90.

Inclusion of these “contracts” and correspondence spuriously increases Mr. Young’s reported number of “contracts not referencing AWP.”

(c) Mr. Young incorrectly identifies and counts some “contracts” (e.g., Aetna Contract number 107 at the bottom of page 21 of 44 in his Exhibit 2.1) as not relying upon AWP; citing “J-Codes provided, fixed dollar amount for LUPRON provided (\$643.77 as of 8/8/02),”² however, the fixed dollar amount cited in the contract *is the AWP*.

(d) ***Mr. Young understates the number of contracts referencing AWP by ignoring those that reference Medicare pricing, Medicaid pricing and FFS pricing, all of which are explicitly AWP-based.*** For example, all Gateway contracts included in his sample (49 in total) are for Medicaid services and pharmaceuticals.³ Accounting for reference to AWP in these government reimbursement rate schedules, an additional 68 contracts, or 33% of his 206, reference AWP.

(e) ***Approximately half of the contracts (49%) provide no supporting information about the specific reimbursement rates.*** This latter category of contracts includes the following: contracts which refer to reimbursement rates in Schedules that are not provided; and contracts which refer to reimbursement rates based upon schedules defined as “maximum allowable amounts,” “usual and customary amounts,” “reasonable, equitable fee schedule (REF),” “actual amounts,” “billed amounts” and/or “compensation schedules” that in fact may be based on or referenced to AWP.

² See AET 004285-86, as cited in Young Sur-Reply Exhibit 2.1, page 21 of 44, the last Aetna contract on that page, under “Comments.”

³ Note further that while these 49 contracts reference AWP (through Medicaid; see Table D.1 in Attachment D of my Affirmative Declaration), since they summarize Medicaid services they are not representative of the Class. Since Mr. Young included them in his sample, I continue to analyze his sample with these contracts included.

(f) Mr. Young plainly picks his document production to generate the results he cites. For example, in his Exhibit 2, he asserts that he has reviewed three contracts for the Three Rivers Health Plans (TRHP); he asserts that none of them reference AWP. *In fact, these three contracts do reference AWP through reference to governmental fee schedules.*

(g) *Furthermore, Mr. Young excludes TRHP contracts that explicitly do reference AWP.* For example, the Bates numbers of the contracts upon which Mr. Young relies are given in his Exhibit 1.⁴ However, the transcript of the September 24, 2004 deposition of David W. Thomas, Vice President and General Counsel of TRHP, refers to a TRHP reimbursement contract that immediately precedes in production sequence the first contract cited by Mr. Young. The relevant deposition Q&A concerning this contract is found at pages 103-105 of the deposition transcript:

“Q: How is the specialty pharmacy compensated for the drug products under this contract?

A: If you look at Attachment A on the pages in the sections that have the J code listings that describe the products, the far right column will specify reimbursement for each of those products, *and the reimbursement for all of them is specified as a percentage of AWP.*

Q: *When you say everything or all of them are specified as a percentage of AWP, is it accurate then that all of these drugs are compensated at some discount off of AWP?*

A: *Yes. This is mathematically the reverse of the statement you see in the other contracts where it was — instead of saying AWP less a percentage, this says a percentage of AWP. It's a varying mathematical manner of expressing the same concept” (emphasis added).*

⁴ The preceding document is TRHAWP000027-49. The three TRHP contracts he cites are numbered in his Exhibit 1 S323, S324 and S325. The bates number ranges on these contracts are sequential: TRHAWP000050-66; TRHAWP000067-83; and TRHAWP 000084-105.

Hence, Mr. Young has mischaracterized the three TRHP contracts he reviewed. He has excluded a fourth TRHP contract that explicitly contradicts his assertions; a contract that simply could not have been overlooked by an expert doing an appropriate examination of the relevant contracts for a report to be submitted to this Court.

(h) Mr. Young neglected discovery materials, including contracts that indicate reimbursement of physician-administered drugs is based on AWP. Listed below are just a few examples of such documents that Mr. Young chose not to cite in Exhibit 2 of his Declaration:

- A contract between Blue Cross Blue Shield of Tennessee and a specialist physician includes an attachment that outlines reimbursement in accordance with the practice that ***“Maximum Allowable Fee Schedule is based on Average Wholesale Price (AWP)”*** (FCC 000485-96 at FCC 000495). Attached hereto as Exhibit A (emphasis added).
- An amendment to a contract agreement between Unicare Life & Health Insurance and Texas Cancer Care states, “Pharmacy (including infusion therapy drugs): maximum allowable reimbursement based on average wholesale price (AWP) according to UNICARE selected published market data, including, but not limited to, sources such as the Drug Topics Red Book” (TCC 000473-90 at TCC 000474). Attached hereto as Exhibit B (emphasis added).
- An appendix to a contract agreement between United Healthcare of Texas and Southwest Physician Associates states that the fee maximum for pharmaceuticals will be ***“100% of AWP”*** (TCC 000981-1000 at TCC 001000). Attached hereto as Exhibit C (emphasis added).

- A contract agreement between Better Health Plans, Inc. and a “Consulting Physician” includes an amendment that states, “**Health Plan shall compensate Consulting Physician at 90% of the Average Wholesale Price (AWP) for all drugs. These drugs shall be billed with the appropriate NDC codes**” (FCC 000595-614 at FCC 000613). Attached hereto as Exhibit D (emphasis added).
- Five additional contracts involving Premera Blue Cross, which are attached as Exhibit E, reference AWP.⁵

(i) Even when cited by Mr. Young, his evaluations of the contracts are unreliable. To demonstrate, I present in my Exhibit F a chart showing a sample of ten different physician contracts and/or amendments referenced by Mr. Young in his Exhibit 2. My Exhibit F reiterates Mr. Young’s summary of these 10 contracts and provides an additional column of information correcting Mr. Young’s incorrect analysis. The Exhibit illustrates that Mr. Young has made significant errors in his characterization of these contracts. Proper review of this sample of contracts demonstrates that Mr. Young’s Exhibit 2 has misrepresented the content of these contracts; the reimbursement rates cited therein do indeed reference AWP, either explicitly or through reference to other amendments or to government rates. Without closer and careful scrutiny, it is impossible to discern whether Mr. Young’s mischaracterization is limited to this sample or occurs consistently throughout his analysis.

6. **Mr. Young’s discussion of the contracts presented in his Exhibit 2 is not analysis.** He has gathered contracts, many of which do not even relate to pharmaceutical reimbursement, and apparently only checked to see whether the acronym AWP appears in the

⁵ See PBC 00200-43 attached as Exhibit E.

document. *In some cases, he has characterized some contracts as not referencing AWP when they do indeed reference AWP.*

Specifically, in Exhibit G, I have reiterated his Exhibit 2, but have corrected the many mischaracterizations that he incorporates into his Exhibit. Note the following:

- (a) 8% of the contracts pre-date the Class Period and are irrelevant to this matter;
- (b) 6% explicitly reference AWP;
- (c) 33% reference AWP through explicit reference to governmental fee schedules (Medicare, Medicaid and FFS, all of which reference AWP);
- (d) 4% refer to capitated schedules; and
- (e) 49% refer to fee schedules that are not included or are based upon “maximum allowable amounts,” “usual and customary amounts,” “reasonable, equitable fee schedules (REF),” “actual amount,” “billed amount,” and “compensation schedules” that do not necessarily preclude AWP pricing.
- (f) For those contracts for which no reimbursement rate schedule is provided, *it is logically impossible to draw Mr. Young’s conclusion* that reimbursement rates summarized in these missing reimbursement rate schedules do not reference AWP. Likewise, for all other contracts that reference reimbursement rates characterized as “maximum allowable amounts,” “usual and customary amounts,” “reasonable, equitable fee schedules (REF),” “actual amount,” “billed amount,” and “compensation schedules,” *it is impossible to draw the conclusion that these contracts do not reference AWP without examining the relevant rate schedules.*

7. Such a conclusion is shown to be patently incorrect as the more complete survey analyses that are available demonstrate that *AWP is the reference point for reimbursement rates*

(regardless of whether they are called “maximum allowable amounts,” “usual and customary amounts,” “reasonable, equitable fee schedules (REF),” “actual amount,” “billed amount,” or “compensation schedules”) *for commercial payors for physician-administered drugs*. One survey was conducted by Dyckman & Associates⁶ for the Medicare Payment Advisory Commission, or MedPAC; the other survey was conducted by the University of Chicago and the Health Policy Institute of Georgetown University⁷ for MedPAC. Both studies were relied upon by MedPAC at some length in their June 2003 Report to the U.S. Congress. Mr. Young is aware of these survey analyses; he addresses the MedPAC study in his Sur-reply.

(a) The survey conducted by Dyckman and Associates surveyed 33 large private health plans including Blue Cross Blue Shield plans and national managed care plans whose covered lives represented over one fifth of those with private insurance in the United States (40 million lives). The study conducted by the National Opinion Research Center (NORC) at the University of Chicago (in conjunction with the Health Policy Institute at Georgetown) surveyed a range of stakeholders in the market for physician-administered pharmaceuticals.

(b) *Each study indicates that average wholesale price (AWP) is used consistently as the basis for reimbursement of physician-administered drugs in the private sector.*

- The Dyckman survey consisted of a set of open-ended questions posed to representatives from the health plans. One was, “How do you set prices for physician-administered drugs?” *Each respondent reported that AWP was one component of their reimbursement formula.* Exhibit 2, on page 3 of the report,

⁶ [http://www.medpac.gov/publications/contractor_reports/Aug03_DrugsPay\(cont\)Rpt.pdf](http://www.medpac.gov/publications/contractor_reports/Aug03_DrugsPay(cont)Rpt.pdf)

⁷ [http://www.medpac.gov/publications/contractor_reports/Aug03_DrugsDist\(cont\)Rpt.pdf](http://www.medpac.gov/publications/contractor_reports/Aug03_DrugsDist(cont)Rpt.pdf)

showed that *32 respondents reimbursed physician-administered drugs as a direct function of AWP, while one respondent used a more complex formula that included AWP.*

- The NORC survey involved a semi-structured interview with respondents including 4 oncologists, 2 health plans, 2 pharmacy benefits managers, 3 specialty pharmacy companies, 1 wholesaler, 1 group purchasing organization and 3 consultants. In the key findings with regard to private insurer reimbursement of physician-administered cancer drugs, the authors identified four types of drug prices typically used as the basis for reimbursement (page 12). The first is based on actual or “dead” acquisition cost, which is said to be the actual amount the physician (or sometime third party payers) paid for the drugs. *The second is AWP. The third is wholesale acquisition cost, which is formulaically related to AWP. The fourth is Medicare allowable cost, which is also based on AWP. The report goes on to say that “most private payers have followed Medicare’s lead and pay physicians based on AWP.”*

(c) *Both surveys contradict Mr. Young’s assertion that commercial payors do not reference AWP when negotiating reimbursement rates for physician-administered drugs.*

8. It appears that Mr. Young has simply not reviewed or chosen not to report other discovery materials explicitly referencing AWP for injectible reimbursement rates. For one example, according to Exhibit 2 to the Declaration of Jessica Barnett in Support of AstraZeneca Pharmaceutical LP’s Individual Surreply in Opposition to Plaintiffs’ Motion for Class Certification provides:

(a) Medicare and Medicaid drug allowances for Lupron for various states either equals AWP or are some percentage of AWP (at AZ0233065-69). This Exhibit also provides the relevant J-code for the procedure. Hence, this document indicates that the relevant commercial payors track both J-codes and NDCs/AWPs of the injectible subject to the claim.

(b) Page AZ0233073 provides more information on the concordance of J-codes and AWPs (i.e., the specific NDC (3.6 mg) of Zoladex).

(c) At page AZ0233075, Exhibit 2 states “Medicare, private payors, and most Medicaid agencies will cover ZOLADEX (goserelin acetate) and the physician services associated with its use. ... Payments will differ among payors but are usually based on the average wholesale price (AWP) as listed in the *Red Book*. Though most insurers will not reveal what amount they will pay, it is typically a percentage of the AWP (often 80 percent)” (emphasis in the original).

III. MR. YOUNG INCORRECTLY ASSERTS THAT COMMERCIAL PAYOR RELIANCE UPON J-CODES IN THEIR CLAIMS DATA MAKES IT IMPOSSIBLE TO REFERENCE THE APPROPRIATE NDCS AND AWPS OF THE SPECIFIC INJECTIBLE DRUGS.

9. In his Sur-Reply, Mr. Young raises the issue of the use of J-Codes for physician-administered drugs. Specifically, he takes insurance claims for physician services within a given J-Code or Q-Code and presents the raw data on reimbursement amounts, which essentially fill the graph. For examples, in his Sur-Reply, he performs this exercise in his Exhibit 3.02 for BCBSTN (Blue Cross Blue Shield of Tennessee) for Procrit-Q0136; in his Exhibit 3.03 for BCBSTN for Remicade J1745; and in Exhibit 3.04 for Taxol J-9265. He produced analogous scatter plots in Exhibit 15 of his Rebuttal Declaration in this matter.

10. He concludes (§§ 44-45): “A health plan does not even know which manufacturers’ product they are reimbursing when a claim is submitted related to a multi-source drug under a J-Code; [and] Medicare also uses J-Codes to reimburse all physician-administered drugs under Part B. Therefore, each of these issues applies equally to physician-administered drug reimbursements under Medicare Part B.”

11. The issue of J-Code (or Q-Code) billing must be addressed, as understood by Dr. Berndt (see his §§ 193-198). However, Mr. Young’s assertions overreach and obfuscate.

12. If we are to believe Mr. Young, physicians submit claims for drug reimbursement and third-party payors (TPPs) pay those reimbursement claims, regardless of the amount requested in the claim and despite the fact that the preponderance of the contractual evidence demonstrates that reimbursement claims reference AWP. If we are to believe Mr. Young, physicians regularly violate their reimbursement contracts by submitting reimbursement claims higher than what is allowed by the referenced AWP (it is difficult to imagine that providers consistently bill less than allowed by contract or bill some random amount) and that commercial payors simply have no idea how the drug reimbursement rate requested in a submitted claim can be evaluated or audited against the relevant contracts and reimbursement fee schedules referencing AWP.

13. Such assertions and conclusions must be viewed skeptically, as a matter of the evidentiary materials and as a matter of business practice.

14. First, let me discuss the evidentiary materials. The evidentiary materials clearly demonstrate that the Class members entered into and relied upon contracts which referenced *AWPs, which by definition were NDC specific. Hence, by contract, Class members relied upon AWP-based drug billings referencing the relevant NDC for each J-Code.*

(a) I have already documented above in Section I (by reference to the MedPAC and NORC surveys and to the summary in my Exhibit G) that TPP contracts generally and those submitted in evidence specifically demonstrate that TPPs expected to be billed at reimbursement rates referencing AWP and that physicians contracted to submit reimbursement claims referencing AWP.

- In my Exhibit G, of the 89 contracts relevant to the Class Period for which actual reimbursement rate information is provided, 91% (81) reference AWP explicitly or through government fee schedules referencing AWP.⁸ Eight contracts (9%) did not reference AWP; those contracts are capitated and reimbursements under those contracts are not part of the Class.
- Another 100 contracts cited by Mr. Young *provide no reimbursement rate schedules*; therefore, no definitive conclusions can be drawn from these contracts regarding reference to AWP (see Section I above). However, while these contracts must be reviewed to draw definitive conclusions, there is no reason to believe that reference to AWP will be different for this group than for the other 89 for which such information is included.

(b) The discovery materials and Mr. Young's own supporting materials make clear that commercial payors can disaggregate the dosage and presentation (*i.e.*, the NDC) of the relevant drug administered by the physician and claimed by the physician for reimbursement by the payor. Illustrations follow.

⁸ Recall that 49 of these contracts are for services provided under Medicaid; see footnote 3 above.

- In the September 14, 2004 deposition of Paula Pfankuch, the representative for Health Care Service Corporation (*i.e.*, Blue Cross Blue Shield of Illinois – BCBS-IL), she states in her transcript:

“Q: Okay. So then for drugs administered in a physician setting, they were subject to the fee schedule?

A: Yes, they are.

Q: ***That's the underlying Medicare base fee schedule [which is AWP-based]?***

A: Yes.

Q: Okay. And then how was that fee schedule derived?

A: That fee schedule is based currently on the dollars that Medicare publishes for those J codes, and we use a percentage of the Medicare allowable.

Q: And how long has that been the methodology which you've used?

A: I believe that's been in place since 1999.

Q: And how did you reimburse for drugs administered by a physician before 1999?

A: ***Prior to 1999 the full service units -- those are our claim payment areas -- utilized the AWP as published in the Red Book.*** I would like to clarify for that last statement that it was a percentage of the AWP published in the Red Book.

Q: Okay. And can you tell me what BlueCross BlueShield of Illinois understood AWP, or average wholesale price, to be?

A: Simply the average wholesale price.

Q: And the average wholesale price, what do you mean by that?

A: Our understanding of it is very limited, at least within the professional reimbursement area. It is simply a term that

we would look to for pricing. There is not a tremendous amount of knowledge about AWP specifically other than it seems to be the industry standard for the baseline reimbursement for physician-administered drugs” (pp. 25-26). (Emphasis added).

- The deposition testimony (pp. 103-105) of David Thomas, cited above, regarding the TRHP reimbursement contract that Mr. Young neglected to review and include, demonstrates that commercial payors are easily able to identify the relevant NDCs of the drug administered by physicians as part of services claimed under a particular J-Code.
- The AstraZeneca (AZ) documents cited above (in Section I) demonstrate the concordance of NDCs and J-Codes for Zoladex for all states. The same concordance is evident for BCBS of Tennessee in Attachment D.3 of my December 16, 2004 Rebuttal Declaration. Additional AZ discovery materials attached as Exhibits to the Barnett Declaration (cited above) demonstrating the industry’s methods for identifying NDCs within J-Codes are found at AZ0427834 (where AZ discusses how to add additional numbers to the J-codes to differentiate among alternative dosages) and at AZ0427839-44.

(c) The following documents show that the reliance upon NDC-specific AWP within J-codes in pharmaceutical reimbursement contracts is common and routine. Each of these documents provides an example where covered pharmaceuticals are identified in terms of J-codes and the reimbursement of those codes is set in relation to AWP. Although Mr. Young has cited a variety of documents from some of these entities and others, he does not cite a single document listed below in his Exhibit 2.

- A Blue Cross Blue Shield of Texas Physician Contract with Specialty Injectable Drug Program showing J- and Q-Code pricing in terms of AWP-30% to AWP-15% (TCC 000354-000361 at TCC 000356-000361). Attached hereto as Exhibit H.
- A Letter from Baptist & Physicians IDS announcing reimbursement for administered plans of HCPCS⁹ J-Codes at AWP (FCC 000299). Attached hereto as Exhibit I.
- An AmCare Health Plans of Texas, Inc. Specialty Care Physicians Services Agreement that provides that HCPCS J-Codes will be reimbursed at AWP+10% (TCC 000249-000286 at TCC 000267). Attached hereto as Exhibit J.
- An amendment to a provider group agreement between Beech Street Corporation and Southwest Physicians Associates that provides a fee schedule that calls for J-Codes to be reimbursed at the lesser of billed charges or 100% of AWP per *Red Book* current version (TCC 000365-000386 at TCC 000369). Attached hereto as Exhibit K.
- A letter with amendments to an oncology clinic from Aetna providing all J-Codes to be reimbursed at 100% of AWP (SPH 002023-002026 at SPH 002025). Attached hereto as Exhibit L.

(d) Common practices and procedures have been developed to allow providers to submit claims by J-Code and allow payors to relate those J-Code-based claims to the appropriate AWP. The practices and procedures make use of *fundamental billing units (FBUs)*

⁹ That is, Health Care Common Procedure Coding System.

*which are assigned by CMS.*¹⁰ Exhibit M presents the fundamental-billing-unit dose (FBU dose) and the associated fundamental-billing-unit AWP (FBU AWP) for each NDC of each brand-name physician-administered drug presented in Table 1.B of my Affirmative Declaration. Note that when the dosage and FBU AWP of each NDC is adjusted for the number of FBUs designated for that J-Code, each NDC has essentially the same FBU AWP.

(e) This information can be used during the Damages Analysis to provide a crosswalk between NDCs and J-Codes. Manufacturer data on AWP and ASPs will provide the actual spreads necessary to compare (by NDC) with the yardstick spreads, as described in my Affirmative Declaration. The results will be but-for AWP by NDC. Those but-for AWP by NDC can be translated into a weighted average but-for FBU AWP by J-Code. To the extent that the FBU AWP is inflated by the AWP Scheme, reimbursement rates calculated as a percentage of the FBU AWP will be inflated above the reimbursement rate calculated as a percentage of the but-for FBU AWP. The difference between the actual and but-for reimbursement rates applied to all FBUs within a given J-Code sold by a manufacturer and reimbursed by Class members will provide the measure of aggregate class-wide damages.

15. Second, let me discuss the business practices implied by Mr. Young's assertions.

Given the general finding of contractual reference to AWP for physicians and TPPs for physician-administered drugs, the assertion that the claims data do not have any correspondence to AWP suggests the following:

(a) As a matter of business practice, physicians and provider groups consistently violate their contracts and request payments deviating from the AWP-based

¹⁰ The fundamental billing units are used by Mr. Young in his Sur-Reply in Exhibit 15. They are sometimes simply referred to as "billing units" by CMS.

schedules referenced in those contracts. If they are engaging in such a violation, it is implausible to assume that they are billing less than what has been negotiated by contract, or that they are merely billing some random amount un-related to the contract. Neither practice is plausible. If providers are billing more than allowed under contract, the damages calculated for this litigation will compensate payors for the overcharges induced by Defendants' fraud to inflate the AWP but will not compensate them for the additional overcharges induced by such a provider scheme, if such a scheme existed, since it is not part of this litigation.

(b) As a matter of business practice, TPPs take no advantage of information they clearly possess (as identified in ¶ 14 above) relating reimbursement rates to the AWP of specific NDCs for J-Code procedures. Given that deponents have admitted to doing just this concordance (even if laboriously and by hand) and that information exists to support this concordance (see ¶ 14.(d) above), it is implausible to assert that this cannot be done or is never done. It may not be preformed systematically, because of the phenomenon of the "importance of being unimportant," as Dr. Berndt has posited. However, if that is the case, and by ¶ 15.(a) above, providers are billing at the contractually-agreed upon AWP-reference point (or above), then the relevant Class members are being injured in precisely the way described in my Affirmative and Rebuttal Declarations.¹¹

16. One can only reasonably conclude that providers will submit claims at least as high as is allowed by contracts, the preponderance of which reference AWP, based upon the preceding discussion. Payors will either review those claims closely or not, and will either overpay (if over-billed) or will pay the reimbursement related to AWP.

17. In all cases, if the AWP is artificially inflated as alleged, the Class will be injured.

¹¹ See my Affirmative Declaration (¶¶ 10-11) and my Rebuttal Declaration (¶¶ 15-17).

IV. IMPLICATIONS OF THE USE OF J-CODES FOR CALCULATION OF CLASS-WIDE AGGREGATE DAMAGES FOR PHYSICIAN-ADMINISTERED DRUGS

18. Given my response to Mr. Young in the preceding two Sections, let me return to and clarify more fully the implementation of my proposed formulaic damage methodology.

(a) At this stage of the litigation, it remains my understanding that I must identify a formulaic methodology or methodologies to accurately calculate aggregate class-wide damages. *I have done so* in ¶¶ 22-25 of my Affirmative Declaration. I have demonstrated a method that will be used to calculate aggregate class-wide damages, *for each of three groups of drugs*, relying on NDC-level AWP and ASP data from manufacturers' (for actual spreads), in addition to yardsticks that reflect *average market-wide expectations for those groups of drugs* (single-source brand-name self-administered drugs, multi-source generic self-administered drugs and physician-administered drugs). While some further disaggregation of the yardsticks within one (or more) of these three groups of drugs may be possible and analytically useful,¹² it is important to remember that the yardsticks must *summarize average market expectations over time during the Class Period*. For the most part, within-group variation will be addressed during the Claims Administration Phase.

(b) As demonstrated above, Mr. Young has mischaracterized the evidence concerning the actual contractual reliance of TPPs and providers upon AWP for reimbursement for physician-administered drugs. This reliance was corroborated by Dr. Berndt (at pp. 15, 23-24). Assuming that physicians and providers billed at least what they were allowed to bill under

¹² Dr. Berndt identifies some of the possible sources of such within-group variation at pp. 17 and 48 of his Report. It is not out of the question that some small subset of these specific variations could be used to differentiate yardsticks within groups. The extent to which such differentiation is useful can only be determined at the Damages Phase, when a more complete analysis is conducted. If useful, it will be easily accommodated within my formulaic damage methodology.

contract (which is certainly reasonable), we can safely assume that most, if not all, providers submitted reimbursement claims equal to or above their negotiated percentage of AWP.

(c) Since the AWP's will be known and estimable for all physician-administered NDCs, and since the relevant yardsticks will have been calculated for physician-administered drugs as a whole (or for a select set of sub-groups of physician-administered drugs), *but-for AWP's* will be calculated using the methods proposed in my Affirmative Declaration and the percentage AWP inflation induced by the fraud will be readily calculated for each NDC.

(d) While the precise use of these calculations in the actual measurement of class-wide damages will be finalized during the Damages Phase, two candidate methods can be identified at this time. As the actual Damages Analysis unfolds, refinements of these methods may reveal themselves.

V. METHOD 1

19. Assuming that physicians and providers do indeed bill payors for pharmaceuticals administered in an out-patient setting at the maximum amount allowed by contract (it is implausible to assume otherwise), that billing would be at some percentage of AWP.¹³ The percentage will be calculated during the Damages Phase by a representative sample of payors *and their contracts*. The result will be analogous to the finding of MedPAC; that is, the reimbursement rate paid is some percentage of AWP billed and paid by third-party payors, averaged over payors and physician-administered drugs.¹⁴

¹³ Again, if providers billed for more than the percentage of AWP allowed under contract, that would involve additional contractual damages not subject to this litigation.

¹⁴ The MedPAC analysis cited in my Affirmative Declaration, Attachment D (¶ 30) finds the reimbursement rates for physician-administered drugs range from 85% - 115% (the weighted average of which is 97.55%) of AWP; see also ¶ 7 above.

20. Given this assumption and given the analysis leading to the calculation of the but-for AWP, the average actual and but-for reimbursement rates can be calculated for all NDCs subject to all J-Codes. Aggregate class-wide overcharge damages can be readily calculated using my formulaic damage methodology.

21. The information requirements for this method are aggregate manufacturer unit sales data by NDC for all physician-administered drugs subject to the Complaint, their respective AWPs and the representative sample of payors and payor contracts.

VI. METHOD 2

22. Making the same assumptions as those upon which Method 1 is based, Method 2 analyzes more fully the variation in claims information across Class members. Under Method 1, this analysis would be deferred to the Claims Administration Phase.

23. Under Method 2, a more comprehensive representative sample of payors conducted during the Damages Phase would identify four groups of payors and quantify the following: (1) the percentage of payors contracting for AWP-based reimbursement who can precisely translate invoiced J-Code-based claims to specific NDCs;¹⁵ (2) the percentage of payors contracting for AWP-based reimbursement who rely upon the fundamental-billing-unit information for evaluating and reimbursing claims within a given J-Code;¹⁶ (3) the percentage of payors contracting for AWP-based reimbursement who do not translate J-Code-based claims to NDCs nor rely upon FBUs but rather rely upon the “honor system,” that is, that providers bill as contracted; and (4) the percentage of those payors who contract for AWP-based reimbursement,

¹⁵ As discussed above in Section II, Mr. Young has mischaracterized and understated the pervasiveness of the ability of Class members to crosswalk claims under J-Codes to the relevant NDCs and AWPs.

¹⁶ See ¶ 14.(d) above and Exhibit M.

invoice under J-Code-based medical benefit reimbursements but do not critically evaluate or simply have no idea about the NDC of the claimed drug or the reimbursement amount paid.

24. For the first group, claims under J-codes can be translated into specific NDCs and AWP and damages calculated from the formulaic damage methodology described in my Affirmative Declaration. The damages would be applicable to the percentage of all units reimbursed by this group of payors, as calculated through survey.

25. For the second and third groups, the payors are found not to undertake any type of analysis relating J-Codes to NDCs. They either track FBUs and the FBU AWP or they rely on the "honor system." Depending upon the mix (by NDC) of out-patient claims reimbursed by this group by J-Code, this group of payors will suffer aggregate overcharge damages determined by the AWP inflation by NDC and the mix of NDCs reimbursed under the relevant J-Code. The NDC-specific overcharges are determined by manufacturer data and the yardsticks. The weights of these NDC-specific overcharges within J-Codes will be determined by TPP sample¹⁷ or by total manufacturer sales by NDC and/or by FBUs. The result will be a but-for FBU AWP by J-Code for all reimbursements for these two groups. The aggregate damages for these two groups then will be calculated using my formulaic damage methodology as discussed more fully in ¶ 14.(d) above. The representation (percentage share) of these TPPs within the Class will have been calculated by the original sample discussed above.

26. Finally, for those TPPs (the fourth group) that are found by survey to ignore AWP in their contracts generally and/or to uncritically reimburse at rates unrelated to AWP (even though the contracts are so written), I will simply exclude that percentage of units sold by

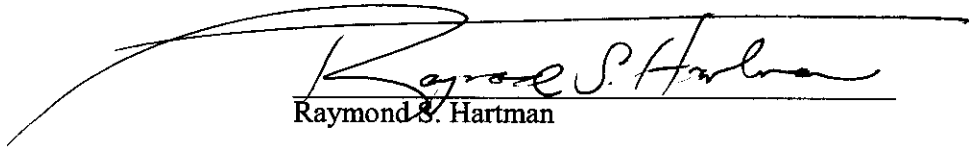
¹⁷ One source of the sample information is the sample gathered for the first two groups of payors. Others will be investigated during the Damages Phase.

J-Code from aggregate sales and therefore from aggregate class-wide damages, since the payors in this group, by definition, are not members of the Class.

27. Both of these methods make use of standard analytical techniques and data. At the time of the Damages Analysis, I will determine which is appropriate; whether both should be conducted; or whether a refinement of the two should be implemented.

I declare under penalty of perjury that this Declaration is true and correct.

Executed on March 9, 2005.



Raymond S. Hartman